

Regulations Development and Preliminary Recommendation for Laboratory Accreditation Standard

Christine Sotelo, Chief
Environmental Laboratory Accreditation Program
State Water Resources Control Board
Public Workshop - October 6, 2016

Agenda

1. **Christine Sotelo**, Environmental Laboratory Accreditation Program
2. **Bruce LaBelle**, State Agency Partner Committee
3. **Andy Eaton**, Environmental Laboratory Technical Advisory Committee
4. **David Kimbrough**, Coalition of Accredited Laboratories
5. **Robert Brownwood**, Division of Drinking Water
6. **Public Comment Period**

Expert Review Panel Report Recommendations

- Establish a management system
- Ensure use of relevant methods
- Expand resources
- Enhance communication with stakeholders
- Adopt laboratory accreditation standard

Establish a Management System

- Expert Review Panel identified that we need transparent and consistent operating procedures
- We adopted The NELAC Institute (TNI), Volume 2
- We have written 20 Standard Operating Procedures
 - Currently test-driving and refining

Ensure Use of Relevant Methods

- Expert Review Panel identified we were using methods 25 years out-of-date
- We now have new lists
- The new lists are more functional
 - Able to be updated as environmental monitoring needs change

Expand Resources

- Expert Review Panel identified that ELAP staff lacked the qualifications to perform their jobs
- The Board is investing in creating the top assessor training program in the country
 - Three years of training and shadowing professional assessors
- Created new unit to evaluate Proficiency Testing samples

Enhance Communications

- Panel identified we had poor interactions with laboratories and our regulatory agency clients
- We created a strategic communications plan
- We rebuilt our Environmental Laboratory Technical Advisory Committee
- We created a State Agency Partner Committee

Expert Review Panel Report Recommendations

- Establish a management system
- Ensure use of relevant methods
- Expand resources
- Enhance communication
- **Adopt laboratory accreditation standard**

Options discussed by our two advisory bodies

- Add U.S. Environmental Protection Agency requirements to current regulations
- Use another state's requirements
- Create a new, California-specific system
- Adopt ISO 17025
- Adopt requirements from The NELAC Institute (TNI) Standard, Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis (2016)

Preliminary Recommendation

- ***Use the 2016 TNI Standard as the base of our laboratory accreditation standard management system requirement by incorporating the document by reference into regulation***
- Consider revisions to select elements that the laboratory community finds to have the worst cost-benefit
- Develop a compliance assistance program for laboratories to smooth the transition

State Agency Partners Committee

- Made up of representatives of California Regulatory Agencies
 - These are our primary clients
- Have met five times since March

State Agency Partners Committee

- Department of Toxic Substances Control
- State Water Resources Control Board
- Regional Water Quality Control Boards
- Department of Public Health
- Department of Pesticide Regulations
- Department of Fish and Wildlife



Environmental Laboratory Technical Advisory Committee

- Comprised of 14 voting representatives from the accredited laboratory community
 - These are experts who provide technical advice on issues that affect laboratories
- Have held five meetings since March

ELTAC Voting Members

Voting Member	Representing
Mindy Boele	Northern California - California Water Environmental Association (CWEA)
Jill Brodt	Small, Northern California commercial laboratories
Stephen Clark	Specialty laboratories
Ronald Coss	Southern California - California Water Environmental Association (CWEA)
Huy Do	California Association of Sanitation Agencies (CASA)
Andy Eaton (Chair)	Large, multistate commercial laboratories
Miriam Ghabour	Large, municipal laboratories
Bruce Godfrey	American Council for Independent Laboratories (ACIL)
Anthony Gonzalez	California Association of Public Health Laboratory Directors (CAPHLD)
Rich Gossett	Commercial and academic laboratories
David Kimbrough	Small, Southern California municipal laboratories
Mark Koekemoer	Small, Northern California municipal laboratories
Allison Mackenzie	Medium/large, California commercial laboratories
Gilda Neshvad	Hazardous waste laboratories

Defining a “Laboratory Accreditation Standard” – 3 elements

1. Technical Requirement – Analytical Test Method

- Laboratories must prove they are capable of performing procedures in an approved test method

2. Monitoring Requirement – Proficiency Testing

- Laboratories must analyze blind performance evaluation samples to confirm they are producing acceptable data

3. Management Requirement – Quality Management System

- Laboratories must document the processes, procedures, and responsibilities necessary for achieving quality policies and objectives

We Have Resolution - (On 2 of 3 elements)

1. Monitoring Requirement – Proficiency Testing

- ELAP will require laboratories pass one proficiency test per year
- *Both advisory bodies agree*

2. Technical Requirement – Analytical Test Method

- ELAP will require laboratories perform the procedures and quality control/quality assurance in approved test methods
- *Both advisory bodies agree*

One element remaining – Management Requirement

- Both advisory bodies agree - A quality management system should be required as a condition of accreditation in California

BUT, the Committees disagree on **which** quality management system to use.

What did the committees recommend?

- State Agency Partners Committee recommended requiring the 2016 TNI Standard
 - One dissenting opinion
- ELTAC identified two primary options
 - Add requirements from US EPA documents to current regulations – 7 votes
 - Use the TNI Standard and consider revising elements the laboratory community finds to have the least value – 6 votes

Why Agency Partners Want TNI

- It is a consensus-based standard
 - Created and vetted by a diverse group of industry experts and stakeholders
- Ready for adoption NOW
- Training and implementation resources are readily available
- Fulfills need for legally defensible data through documentation requirements
- Provides a sustainable solution for the future

Agency Partners Caveat

- Agency Partners recognize this may be a big change for some laboratories
- Open to phased implementation
- Would like to work with ELTAC to prioritize elements and create an implementation schedule

Why ELTAC is Split

- California has two major classes of laboratories
 - 80% small laboratories
 - 20% large laboratories, mostly commercial
- Small laboratories are concerned about the cost of implementation
- Large commercial laboratories are concerned with business needs
 - A standard consistent with many other states is beneficial to them

Basis for our recommendation

- State Agency Partners want the TNI Standard
 - They are our primary clients
- But, we recognize the concerns of the small laboratory community
 - Will consider revising select elements identified as having the least value
- Benefits of using the TNI Standard were outlined in the State Agency Partner Committees reasoning

What do we mean by “revise”?

- Not require sections
- Adjust requirements of sections
- Delay implementation of select sections

How we will decide on revisions?

- We have asked ELTAC to identify sections for consideration of revision
 - We'll discuss proposals at their November meeting
- Verify with State Agency Partners Committee that modifications do not lessen the value of certification to their agencies

Concerns expressed about the TNI Standard

- The document must be purchased
- Documentation requirements are unnecessary
- Requirements are not relevant to small laboratories
- The cost of implementation could cause laboratory closure or consolidation

The TNI Standard must be purchased

- We understand the concern
 - However, we also recognize that laboratories already use other copyrighted documents as part of routine laboratory operations
- We have negotiated preferred rates for California laboratories

Documentation requirements are unnecessary

- We disagree
 - More importantly, ELAP's clients disagree
 - They specifically called out the documentation requirements as meeting their legal need to be able to historically recreate data
- Still, we have opened the door for revising sections that provide the least value

Requirements are not relevant to small laboratories

- We disagree
 - Small laboratories are most vulnerable to inconsistencies in approach when there is employee turnover
- We have heard testimony from several small laboratories from across the country
 - They found the implementation process valuable to their operations
 - Saw an improvement in data quality

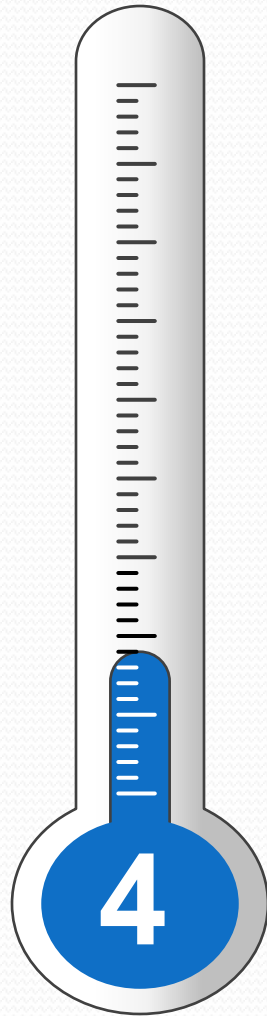
The cost of compliance could cause laboratory closure or consolidation

- Yes, it is a possibility
 - Particularly for the smallest laboratories
- We are committed to working with laboratories to minimize the cost of compliance
 - Free templates
 - Free training
 - Free on-site assistance
 - Extended compliance date

What happens next?

- Today – preliminary recommendation
- Next – California rulemaking process

Regulations Readiness Level



12. Regulations Become Effective
11. Submit to OAL for Final Review
10. Submit for Water Board Consideration
9. Notice of Publication
8. Obtain Approval of Regulation Package for Submittal to OAL
7. Prepare Draft Regulation Package
6. Hold Stakeholder Regulations Workshops
5. Develop Draft Regulation Text
4. **Select Accreditation Standard**
3. **Evaluate Recommendations from Advisory Committees**
2. **Assess Feasibility Through Stakeholder Outreach**
1. **Research Accreditation Standard Options**

Develop Draft Regulation Text

- Developed by ELAP Staff
 - With advice from ELTAC and State Agency Partner Committees
- Consult with Division of Drinking Water Executive Management
- Draft text is publicly released for stakeholder review

Hold Stakeholder Regulations Workshops

- ELAP hosts Stakeholder Regulations Workshops to receive comments on draft text
 - Redding, Sacramento, Fresno, Los Angeles, and San Diego
- Stakeholder Input Period
- ELAP considers revisions in response to stakeholder comments
 - With guidance from ELTAC and State Agency Partner Committee

Prepare Draft Regulation Package

- ELAP staff finalizes the draft regulation package, including:
 - Proposed Text
 - Initial Statement of Reasons
 - Economic and Fiscal Impact Statement
 - Notice of Proposed Regulatory Action

Obtain Approval of Regulation Package for Submittal to Office of Administrative Law

- Regulations must be reviewed and approved by:
 - Division of Drinking Water Executive Management
 - California Environmental Protection Agency Executive Management
- If approved, regulation package is submitted to Office of Administrative Law (OAL) for review
- OAL is the agency responsible for reviewing all administrative regulations
 - Ensures compliance with the Administrative Procedures Act (APA)
 - APA is designed to ensure the public has meaningful opportunity to participate in the regulations adoption process

Notice of Publication

- Official Notice Published by OAL
 - Proposed Text is published
 - Begins a 45-Day Comment Period
 - Formally notices the required Public Hearing
 - Will be at a State Water Board Meeting
- **Stakeholder Input Period**
 - **Formal 45 Day OAL Comment Period**
 - **State Water Board Meeting**
- ELAP and State Water Board receive and consider comments

Changes Made to Text?

- Major Changes
 - Requires another 45 Day Comment Period and Public Hearing
 - **Stakeholder Input Period**
 - **Formal 45 Day OAL Comment Period**
 - **State Water Board Meeting**
- Substantial and Sufficiently Related Changes
 - Requires 15 Day Comment Period
 - ELAP publishes Notice and Text of Proposed Changes
 - **Stakeholder Input Period**
 - **15 Day Comment Period**

Submit for Water Board Consideration

- ELAP prepares Regulations Package
- Hold State Water Board Meeting
 - **Stakeholder Input Period**
 - Board must adopt proposed regulations

Submit to OAL for Final Review

- 30-Day Administrative Review and Approval

Regulations Become Effective

- Final Step
- Approved Regulations Submitted to Secretary of State for filing
- Required compliance date may be different from filing date



Questions?

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